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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,220	06/23/2003	Thomas H. Turpen	LSBC-0087-CP07B	3530

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EXAMINER

RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/602,220	Applicant(s) TURPEN ET AL.	
	Examiner Delia M. Ramirez	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/15/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/23/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/8/05, 9/17/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Claims 6 and 12 are pending.

Applicant's election of Group V, claims 6 and 12 drawn to a polynucleotide encoding the polypeptide labeled rGAL-12, in a communication filed on 12/15/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's amendment canceling claims 1-5, 7-11, and 13-48 in a communication filed on 12/15/2005 is acknowledged.

Specification

1. The Brief Description of the Drawings section in page 19 is objected to due to the recitation of "Figure 12..." and "Figure 13..." for the following reasons. For consistency with the numbering of the drawings, it is suggested that the description of the drawings be amended to indicate "Figures 12-1 through 12-3" and Figures "13-1 through 13-2", or similar. Appropriate correction is required.
2. The specification is objected for not complying with sequence rules. While Figure 5 displays several sequences, neither the drawings nor the Brief Description of the Drawings indicate the corresponding sequence identifiers. Applicant is required to insert the corresponding sequence identifiers in the Brief Description of the Drawings or, in the alternative, amend the drawings to include the sequence identifiers in front of each sequence. See particularly 37 CFR 1.821(d). Appropriate correction is required.
3. The specification is objected to since the reference to prior applications indicated in the first paragraph of the specification does not contain the current status of all nonprovisional parent applications

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to which priority is claimed. See particularly, U.S. Application No. 09/933059, 09/626127, and 09/316572. Appropriate correction is required (MPEP 201.11).

Priority

4. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 120 or 121 to US application No. 09/993,059 filed on 11/13/2001, 09/626,127 filed on 07/26/2000, 09/316,572 filed on 05/21/1999, 08/324,003 filed on 10/14/1994, 08/176,414 filed on 12/29/1993, 07/997,733 filed on 12/30/1992, 08/184,237 filed on 01/19/1994, 07/923,692 filed on 07/31/1992, 07/600,244 filed on 10/22/1990, 07/310,881 filed on 02/17/1989, 07/160,766 filed on 02/26/1988, and 07/160,771 filed on 02/26/1988.

5. SEQ ID NO: 15-16 appear to have been first disclosed in U.S. Application No. 09/993059, filed on 11/13/2001.

Information Disclosure Statement

6. The information disclosure statements (IDS) submitted on 9/17/2004 and 4/8/2005 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Objections

7. Claims 6 and 12 are objected to due to the recitation in claims 1 and 7 of "rGAL-12". Abbreviations unless otherwise obvious and/or commonly used in the art, should not be recited in the claims without at least once reciting the entire phrase for which the abbreviation is used. It is suggested that the claims be amended to recite " SEQ ID NO: 16" in addition to "rGAL-12". Appropriate correction is required.

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8. Claim 6 is objected to due to the recitation in claim 1 of "C-terminus of said polypeptide is the amino acid sequence depicted in SEQ ID NO: 29". Since a polypeptide is a molecule and a sequence is a graphical representation of the order in which residues are arranged in a molecule, a fragment of a polypeptide (i.e., C-terminus) cannot be a sequence. It is suggested that for clarity, the term be amended to recite "C-terminus of said polypeptide consists of the amino acid sequence of SEQ ID NO: 29". For examination purposes, the claim will be interpreted as being directed to a polynucleotide encoding a polypeptide which comprises the amino acid sequence of SEQ ID NO: 16, wherein the C-terminus of said polypeptide consists of SEQ ID NO: 29. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 6 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 6 and 12 are indefinite due to the fact that they depend upon canceled claims (i.e., claims 1 and 7). For examination purposes, the limitations recited in claims 1 and 7 will be included in claims 6 and 12, respectively. Correction is required.

Claim Rejections - 35 USC § 101

12. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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13. Claims 6 and 12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

14. Claims 6 and 12, as written, do not sufficiently distinguish over nucleic acids as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 US 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of “isolated” or “purified” as taught by pages 29-30 (paragraph 95), of the specification. See MPEP 2105.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 6 and 12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 8, 13-15 of copending Application No. 10/984389.

Although the conflicting claims are not identical, they are not patentably distinct.

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Claim 6 of the instant application is directed to a polynucleotide encoding a polypeptide comprising SEQ ID NO: 16, wherein the C-terminus of said polypeptide consists of the amino acid sequence of SEQ ID NO: 29. Claim 12 of the instant application is directed to a polynucleotide encoding a polypeptide consisting of SEQ ID NO: 16. Claims 1-3, 8, 13-15 of copending Application No. 10/984389 are directed to a polynucleotide or viral vector comprising a polynucleotide encoding the polypeptide of SEQ ID NO: 16, the polynucleotide of SEQ ID NO: 15, or a polynucleotide encoding a fragment of α -galactosidase wherein said fragment of α -galactosidase results from the deletion at the C-terminus of one to 25 amino acids. The polypeptide of SEQ ID NO: 16 and the polynucleotide of SEQ ID NO: 15 are the same in both applications. The polypeptide of SEQ ID NO: 16 is encoded by the polynucleotide of SEQ ID NO: 15. The polypeptide of SEQ ID NO: 16 (417 amino acids) is a fragment of the human α -galactosidase (429 amino acids) which lacks the last 12 amino acids of the C-terminus of the human α -galactosidase. SEQ ID NO: 29 is the amino acid sequence of the last 18 amino acids of the polypeptide of SEQ ID NO: 16 (C-terminus). Therefore, the polynucleotide of claims 1-3, 8, 13-15 of copending Application No. 10/984389 anticipate the polynucleotide of claims 6 and 12 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art of Interest

17. Desnick et al. (U.S. Patent No. 5356804, published October 18, 1994; cited in the IDS of 4/8/2005) teach an α -galactosidase (α -galA; SEQ ID NO: 2; 429 amino acids) which comprises the polypeptide of SEQ ID NO: 16 (417 amino acids). The polypeptide of SEQ ID NO: 16 lacks the last 12 amino acids of the polypeptide of Desnick et al. The polypeptide of Desnick et al. would also comprise SEQ ID NO: 29, which is the amino acid sequence of the last 18 amino acids of SEQ ID NO: 16.

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However, the polypeptide of Desnick et al. does not have a C-terminus which consists of the amino acid sequence of SEQ ID NO: 29 since the C-terminus of the polypeptide of Desnick et al. has additional amino acids not present in SEQ ID NO: 29.


Conclusion

18. No claim is in condition for allowance.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
February 28, 2006